

CHAPTER 83*
LABORATORY CERTIFICATION

[Prior to 4/10/96, see 567—Chapter 42]

PART A
GENERAL

567—83.1(455B) Authority, purpose, and applicability.

83.1(1) Authority. Pursuant to Iowa Code sections 455B.113 and 455B.114, a laboratory certification program is required for laboratories performing analyses of samples which are required to be submitted to the department as a result of Iowa Code provisions, rules, operation permits, or administrative orders.

83.1(2) Purpose. The purpose of these rules is to provide the procedures for laboratories to use to apply for certification, to establish laboratory certification fees, and to provide the appropriate methods and references for evaluating laboratory competence including the requirements for laboratories to become certified.

83.1(3) Applicability.

a. The requirements of this chapter apply to all laboratories conducting drinking water analyses pursuant to 567—Chapters 40, 41 and 43 (with the exception of the University of Iowa Hygienic Laboratory). Routine, on-site monitoring for pH, turbidity, and chlorine residual and on-site operation and maintenance-related analytical monitoring are excluded from this requirement.

b. The requirements of this chapter apply to all laboratories conducting underground storage tank analyses for petroleum constituents pursuant to 567—Chapter 135 (with the exception of the University of Iowa Hygienic Laboratory). Routine on-site monitoring conducted by or for underground storage tank owners for leak detection or a nonregulatory purpose are excluded from this requirement.

c. The requirements of this chapter apply to all laboratories conducting analyses of wastewater, groundwater or sewage sludge pursuant to 567—Chapters 63 and 67 (with the exception of the University of Iowa Hygienic Laboratory). Routine on-site monitoring for pH, temperature, dissolved oxygen, total residual chlorine and other pollutants that must be analyzed immediately upon sample collection, settleable solids, physical measurements such as flow and cell depth, and operational monitoring tests specified in 567—subrule 63.3(4) are excluded from this requirement.

567—83.2(455B) Definitions.

“Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources” (1996) is incorporated by reference in this chapter. Chapter 1 of the manual pertains to certification of laboratories analyzing samples of drinking water and incorporates by reference the “Manual for the Certification of Laboratories Analyzing Drinking Water,” EPA document 570/9-90-008, April 1990, and its supplements EPA 570/9-90-008A, October 1991, and EPA 814B-92-0002, September 1992. Chapter 2 pertains to laboratories analyzing samples for the underground storage tank program. Chapter 3 pertains to laboratories analyzing samples for the department’s wastewater and sewage sludge disposal programs.

“Performance evaluation sample” means a reference sample provided to a laboratory for the purpose of demonstrating that a laboratory can successfully analyze the sample within limits of performance specified by the department. The true value of the concentration of the reference material is unknown to the laboratory at the time of analysis.

*Effective date of 5/15/96 delayed 70 days by the Administrative Rules Review Committee at its meeting held May 14, 1996.

PART B
CERTIFICATION PROCESS**567—83.3(455B) Application for laboratory certification.**

83.3(1) Application forms. Application for laboratory certification shall be made on forms provided by the department and shall be accompanied by the fee specified in 83.3(2). The application for certification or renewal of certification shall be made at least 60 days prior to the date when certification or renewal is desired. The department may require submission of additional information necessary to evaluate the application. If the application is incomplete or deficient, evaluation of the application (and lab appraisal) will not be completed until such time as the applicant has supplied the missing information or corrected the deficiency.

83.3(2) Fees and expenses.

a. A nonrefundable fee for the administration, completion of on-site laboratory surveys and assessments, and enforcement of laboratory certification requirements shall be paid with the certification application. Certification will not be issued until the fees and expenses are paid. Out-of-state laboratories will be responsible for paying the expenses of an on-site visit, if required, and the department or its agent will bill the out-of-state laboratory directly for the expenses.

b. The applicable fees shall be based on the type of analytical service provided as follows:

(1) Water supply laboratory certification fees.

1. The fee for microbiological analyses including total coliform, fecal coliform, *E. coli*, heterotrophic bacteria, virus, algae, diatoms, rotifers, and giardia shall be \$600. Laboratories may also be certified for fluoride, nitrate and nitrite with no additional fee (when they are certified for microbiological analyses) providing they are not seeking certification for any other inorganic analyte.

2. The fee for inorganic analyses including nitrate, nitrite, fluoride, arsenic, sodium, and other inorganics shall be \$1,200. However, a laboratory certified to conduct inorganic analyses under the wastewater program can be certified to conduct inorganic analyses under the water supply program for an additional \$300 (\$1,500 total).

3. The fee for volatile organic chemical analyses such as benzene, vinyl chloride, trichloroethylene, chloroform, and toluene shall be \$1,200. However, a laboratory certified to conduct analyses for volatile organic chemicals under the wastewater program can be certified to conduct analyses for synthetic organic compounds under the water supply program for an additional \$600 (\$1,800 total).

4. The fee for synthetic organic chemical analyses, other than for volatile organic chemicals, such as atrazine, alachlor, 2-4 D, 2-4-5 TP, and lindane shall be \$1,200. However, a laboratory certified to conduct analyses for synthetic organic chemicals under the wastewater program can be certified to conduct analyses for synthetic organic chemicals under the water supply program for an additional \$600 (\$1,800 total).

5. The fee for chemical analyses for dioxins shall be \$600.

6. The fee for asbestos fiber analyses shall be \$300.

7. The fee for analyses of radionuclides shall be \$300. However, a laboratory certified to conduct radionuclide analyses under the wastewater program may be certified to conduct the same analyses for the water supply program for an additional \$100 (\$400 total).

(2) Underground storage tank laboratory certification fees. The fee for analyses for petroleum constituents using methods OA-1 and OA-2 shall be \$1,200. However, a laboratory certified to conduct analyses for petroleum constituents under the wastewater program can be certified to conduct the same analyses for the underground storage tank program for an additional \$300 (\$1,500 total).

(3) Wastewater program laboratory certification fees.

1. The fee for analyses of basic wastewater constituents which includes biochemical oxygen demand (BOD), carbonaceous biochemical oxygen demand (CBOD), total suspended solids (TSS), and ammonia nitrogen (NH_3) shall be \$300.

2. The fee for microbiological analyses shall be \$600.

3. The fee for effluent toxicity analyses shall be \$600.

4. The fee for inorganic analyses shall be \$300 per analyte to a maximum of \$1,200. However, a laboratory certified to conduct inorganic analyses under the water supply program can be certified to conduct inorganic analyses under the wastewater program for an additional \$300 (\$1,500 total).

5. The fee for synthetic organic chemical analyses, other than volatile organic chemicals, shall be \$1,200. However, a laboratory certified to conduct analyses for synthetic organic chemicals under the water supply program can be certified to conduct analyses for synthetic organic chemicals under the wastewater program for an additional \$600 (\$1,800 total).

6. The fee for volatile organic chemical analyses shall be \$1,200. However, a laboratory certified to conduct analyses for volatile organic chemicals under the water supply program can be certified to conduct analyses for volatile organic compounds under the wastewater program for an additional \$600 (\$1,800 total).

7. The fee for analyses for petroleum products using methods OA-1 or OA-2 shall be \$1,200. However, a laboratory certified to conduct analyses for petroleum constituents under the underground storage tank program can be certified to conduct the same analyses for the wastewater program for an additional \$300 (\$1,500 total).

8. The fee for analyses of radionuclides shall be \$300. However, a laboratory certified to conduct radionuclide analyses under the water supply program may be certified to conduct the same analyses for the wastewater program for an additional \$100 (\$400 total).

(4) The fee for certification of a single analyte, or for any analyses not covered by subparagraphs (1) to (3), shall be \$300.

c. The fee for certification shall not be reduced if an on-site visit is not performed.

d. The laboratory certification fees shall be increased by \$300 per visit in those cases where multiple on-site visits or multiple samples of unknown contaminants (for laboratory performance testing) are necessary.

e. Payment of fees. Fees shall be paid by check or money order made payable to the Iowa Department of Natural Resources. Purchase orders are not an acceptable form of payment.

83.3(3) Reciprocity. Reciprocal certification of out-of-state laboratories by Iowa, and of Iowa laboratories by other states, is encouraged. However, where an out-of-state laboratory has received an on-site visit within its own state, the fee for certification shall not be reduced if an on-site visit is not performed by Iowa.

567—83.4(455B) Procedure for initial laboratory certification for wastewater laboratories.

83.4(1) Implementation process. All laboratories seeking certification to perform wastewater analyses shall provide a letter to the department requesting certification. The letter shall include a statement that the laboratory is capable of performing the analyses for which certification is requested and the intent to participate in blind performance evaluation testing using the approved methods.

a. Laboratories submitting a letter of intent to be certified by October 1, 1996, will be issued a temporary certification letter. The temporary certification will be effective until the laboratory is certified through the on-site visit process or for 120 days (whichever period is longer). No temporary certifications will be issued for applications received after October 1, 1996.

b. The department or its designee will schedule an on-site visit for each laboratory submitting a letter of intent unless the on-site visit is waived by the department as provided by 83.4(1)“e.” The department will request a complete application from the laboratory at least 60 days prior to the on-site visit. The laboratory will have 30 days to complete an application and return it, along with the fee, to the department. Temporary certification will be removed and the on-site visit will not take place if the application and fee are not received.

c. Participation in a performance evaluation test using the approved method(s) for which certification is requested must be initiated within 90 days of submitting the letter of intent to be certified. Performance evaluations consist of analyzing product-spiked samples in a particular matrix provided

by the testing organization to determine if a laboratory's analytical results are within the acceptance range. Acceptable results on the performance evaluation are required in order to receive final laboratory certification. Temporary certification will be removed if the laboratory fails to initiate the performance evaluation. An independent performance testing organization meeting the requirements in the "Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources" (1996) must be used.

d. Certification of the University of Iowa Hygienic Laboratory (UHL) is the responsibility of the UHL quality assurance officer. The quality assurance officer reports directly to the office of the director and operates independently of all areas of the laboratory generating data to ensure complete objectivity in the evaluation of laboratory operations. The quality assurance officer will schedule a biennial on-site inspection of the UHL and review results for acceptable performance. Inadequacies or unacceptable performance shall be reported by the quality assurance officer to the UHL and the department for correction. The department shall be notified if corrective action is not taken.

e. On-site visits. Upon application to the department by a laboratory requesting certification or recertification, the director or designee will contact the laboratory and a date will be established for an on-site visit. The criteria given in the "Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources" (1996) will be used during the on-site visit to evaluate laboratory equipment, procedures, records, and personnel. Prior to the initial on-site visit the laboratory will be requested to complete a presurvey information form. The on-site visit requirement may be waived for out-of-state laboratories desiring certification where EPA or the resident state has a certification program equivalent to Iowa's, an on-site visit has been conducted, and a copy of the on-site visit report can be provided to the department.

83.4(2) Letter of certification. If it is determined that the physical facilities and equipment of the laboratory meet the criteria set forth in the "Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources" (1996) and the laboratory personnel have properly demonstrated proficiency with the procedures specified in the manual, the laboratory will be issued a letter of certification. The letter of certification will state the personnel, parameters and analytical methods for which the laboratory is certified and may contain conditions deemed necessary by the department to ensure that the laboratory is meeting all requirements of this chapter.

567—83.5(455B) Procedures for certification of new laboratories or changes in certification.

Laboratories that wish to become certified to conduct testing for an analyte or a method after the deadline for initial certification has passed shall follow the procedures specified in 567—83.6(455B) for laboratory recertification.

567—83.6(455B) Laboratory recertification. Laboratories shall be recertified every two years after initial certification. Applications for recertification must be on forms provided by the department and must be postmarked at least 60 days prior to the renewal date. Applications shall be accompanied by the fee specified in 83.3(2). To be recertified, laboratories must meet the following requirements.

83.6(1) Laboratories must use the approved methodology for all analyses the results of which are to be submitted to the department.

83.6(2) Certified laboratories must satisfactorily analyze performance evaluation samples at least once per year for each analyte by each method for which the laboratory wishes to retain certification unless a performance evaluation sample is not available for the particular analyte or method. Results must be submitted to the University of Iowa Hygienic Laboratory along with a statement of the method used within 30 days of receipt from the vendor.

83.6(3) Laboratories must notify the department, in writing, within 30 days of major changes in personnel, equipment, laboratory facilities, or other major change which might alter analytical capability.

83.6(4) Laboratories must consent to a periodic site visit, normally every two years. However, an on-site visit may be conducted more frequently if the laboratory undergoes a major change, fails a performance evaluation examination sample analysis, or if the department questions an aspect of data submitted which is not satisfactorily resolved.

83.6(5) Period of validity. Certification shall be valid for a period not to exceed two years from the date of issuance, except in the case of reciprocal certification of an out-of-state laboratory. Reciprocal certification shall be valid for a period equal to that of the resident state in which the laboratory is certified, but shall not exceed two years. A laboratory that has submitted a timely and complete application for renewal shall maintain certification until certification is renewed or revoked.

83.6(6) Reporting requirements.

a. Underground storage tank program. Certified laboratories must report to the person requesting the analysis and include the information required in 567—subrule 135.10(2) in their laboratory report.

b. Water supply program. Certified laboratories must report to the department, or an approved designee, on forms provided by the department or by means of a digital electronic computer format acceptable to the department, all analytical test results for public water supplies. Certified laboratories must also report all analytical results to the supplier of water for which the analysis was performed. Results must be reported by the seventh day of the month following the month in which the samples were analyzed except for positive coliform bacteria samples and their associated repeat and follow-up samples. Results of these samples must be reported to the department, and the supplier of water for whom they were analyzed, within 24 hours of analysis. Samples of nitrate and nitrite which exceed the maximum contaminant level (MCL) must also be reported to the department and the supplier of water within 24 hours of the analysis.

c. Wastewater program. Certified laboratories must report to the person requesting the analysis and include the information required in 567—paragraphs 63.2(2) “b” to “e” in their laboratory report.

83.6(7) Performance evaluation and acceptance limits.

a. Underground storage tank program. Achieve quantitative results on annual performance evaluation samples that are within plus or minus 20 percent of the true value for individual compounds (i.e., benzene, ethylbenzene, toluene, xylene by OA-1) and plus or minus 40 percent of the true value for multicomponent materials (i.e., gasoline, diesel fuel, motor oil by either OA-1 or OA-2).

b. Water supply program.

(1) Volatile organic chemical (VOC) performance evaluations—laboratory certification. Analysis for volatile organic chemicals shall only be conducted by laboratories that are certified by EPA or the department or its authorized designee according to the following conditions. To receive approval to conduct analyses for the VOC contaminants in 567—subparagraph 41.5(1) “b”(1), except for vinyl chloride, the laboratory must:

1. Analyze performance evaluation samples which include those substances provided by EPA Environmental Monitoring Systems Laboratory or equivalent samples provided by the department or its authorized designee.

2. Achieve the quantitative acceptance limits for at least 80 percent of the regulated organic chemicals listed in 567—subparagraph 41.5(1) “b”(1), except for vinyl chloride.

3. Achieve quantitative results on the performance evaluation samples that are within plus or minus 20 percent of the actual amount of the substances when the actual amount is greater than or equal to 0.010 mg/l.

4. Achieve quantitative results on the performance evaluation samples that are within plus or minus 40 percent of the actual amount of the substances when the actual amount is less than 0.010 mg/l.

5. Achieve a VOC method detection limit of 0.0005 mg/l.

(2) To receive approval for vinyl chloride, the laboratory must:

- 1. Analyze performance evaluation samples which include vinyl chloride provided by EPA Environmental Monitoring Systems Laboratory or equivalent samples provided by the department or its authorized designee.
 - 2. Achieve quantitative results on the performance evaluation samples that are within plus or minus 40 percent of the actual amount of vinyl chloride.
 - 3. Achieve a method detection limit of 0.0005 mg/l.
- (3) Synthetic organic chemicals (SOCs) performance evaluations—laboratory certification. Analysis under this paragraph shall only be conducted by laboratories that have been certified by EPA or the department or its authorized designee. To receive approval to conduct analyses for the SOC contaminants in 567—subparagraph 41.5(1) “b”(2) the laboratory must:
- 1. Analyze performance evaluation samples which include those substances provided by EPA Environmental Monitoring Systems Laboratory or equivalent samples provided by the department or its authorized designee.
 - 2. Achieve quantitative results on the analyses that are within the following acceptance limits:

Acceptance Limits

<u>Contaminant</u>	<u>(percent)</u>
DBCP	(+ or -) 40
EDB	(+ or -) 40
Alachlor	(+ or -) 45
Atrazine	(+ or -) 45
Benzo(a)pyrene	2 standard deviations
Carbofuran	(+ or -) 45
Chlordane	(+ or -) 45
Dalapon	2 standard deviations
Di(2-ethylhexyl)adipate	2 standard deviations
Di(2-ethylhexyl)phthalate	2 standard deviations
Dinoseb	2 standard deviations
Diquat	2 standard deviations
Endothall	2 standard deviations
Endrin	(+ or -) 30
Glyphosate	2 standard deviations
Heptachlor	(+ or -) 45
Heptachlor epoxide	(+ or -) 45
Hexachlorobenzene	2 standard deviations
Hexachlorocyclopentadiene	2 standard deviations
Lindane	(+ or -) 45
Methoxychlor	(+ or -) 45
Oxamyl	2 standard deviations
Polychlorinated biphenyls (PCBs (as decachlorobiphenyl))	0 - 200
Picloram	2 standard deviations
Simazine	2 standard deviations
Toxaphene	(+ or -) 45
Aldicarb	2 standard deviations
Aldicarb Sulfoxide	2 standard deviations

Aldicarb Sulfone	2 standard deviations
Pentachlorophenol	(+ or -) 50
2,3,7,8-TCDD (Dioxin)	2 standard deviations
2,4-D	(+ or -) 50
2,4,5-TP (Silvex)	(+ or -) 50

(4) Inorganic chemical performance evaluations—laboratory certification. Analysis under this paragraph shall be conducted only by laboratories that have been certified by EPA or the department or its authorized designee. To receive approval to conduct analyses for antimony, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium and thallium, the laboratory must:

1. Analyze performance evaluation samples which include those substances provided by EPA Environmental Monitoring Systems Laboratory or equivalent samples provided by the department or its designee.

2. Achieve quantitative results on the analyses that are within the following acceptance limits:

Acceptance Limits

<u>Contaminant</u>	<u>Acceptance Limit</u>
Antimony	(+ or -) 30% at greater than or equal to 0.006 mg/l
Asbestos	2 standard deviations based on study statistics
Barium	(+ or -) 15% at greater than or equal to 0.15 mg/l
Beryllium	(+ or -) 15% at greater than or equal to 0.001 mg/l
Cadmium	(+ or -) 20% at greater than or equal to 0.002 mg/l
Chromium	(+ or -) 15% at greater than or equal to 0.01 mg/l
Cyanide	(+ or -) 25% at greater than or equal to 0.1 mg/l
Fluoride	(+ or -) 10% at greater than or equal to 1 to 10 mg/l
Mercury	(+ or -) 30% at greater than or equal to 0.0005 mg/l
Nickel	(+ or -) 15% at greater than or equal to 0.01 mg/l
Nitrate	(+ or -) 10% at greater than or equal to 0.4 mg/l
Nitrite	(+ or -) 15% at greater than or equal to 0.4 mg/l
Selenium	(+ or -) 20% at greater than or equal to 0.01 mg/l
Thallium	(+ or -) 30% at greater than or equal to 0.002 mg/l

c. Wastewater program. Achieve acceptable quantitative results on annual performance evaluation samples that are equivalent to those used in the Water Pollution (WP) proficiency program administered by EPA.

567—83.7(455B) Criteria and procedure for downgrading and revoking laboratory certification.

83.7(1) *Criteria for downgrading certification status to conditional.* A laboratory may be downgraded to conditionally certified status for any of the following reasons:

- Failure to analyze a performance evaluation sample annually within Iowa acceptance limits;
- Failure to notify the department within 30 days of changes in personnel, equipment, laboratory facilities or other major change which might impair analytical capability; or
- Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on an on-site visit.

83.7(2) *Procedure for downgrading to conditionally certified status.*

a. If a laboratory is subject to downgrading on the basis of 83.7(1)“a,” the department shall notify the laboratory or owner in writing. The laboratory director will review the problems cited and, within 30 days of receipt of the letter, send a letter to the department specifying what corrective actions are being taken. The department shall consider the adequacy of the response and notify the laboratory by mail of its certification status and may follow up to ensure corrective actions have been taken.

b. If a laboratory failed to analyze a performance evaluation sample within acceptance limits, the department will not downgrade certification if the laboratory identifies and corrects the problem to the department’s satisfaction within 30 days of being notified. On behalf of the department, the University of Iowa Hygienic Laboratory may send the laboratory another unknown sample containing the failed component if no cause was unequivocally found. If the laboratory fails to analyze this second sample within acceptance limits, the department will downgrade the laboratory to conditional certification and notify the laboratory in writing.

c. Once the department notifies a laboratory, in writing, that it has been downgraded to conditional certification, the laboratory must correct the problem within three months for procedural or administrative deficiency and within six months for equipment deficiency. If the laboratory was downgraded because of a failure to analyze a performance evaluation sample within the acceptance limits, the laboratory must correct the problems and satisfactorily analyze another performance evaluation sample within two months of being notified.

83.7(3) *Criteria for revoking certification status.* Certification may be revoked for cause including, but not limited to, the following and the department retains the discretion to either downgrade or revoke certification. Laboratory certification will be revoked for the following reasons:

a. For conditionally certified laboratories, failure to analyze a performance evaluation examination sample within Iowa acceptance limits;

b. Failure to satisfy the department that the laboratory has corrected deficiencies identified during the on-site visit within three months for a procedural or administrative deficiency or within six months for an equipment deficiency;

c. Submission of a performance evaluation sample to another laboratory for analysis;

d. Falsification of data or other deceptive practices;

e. Failure to use required analytical methodology for analyses submitted to the department;

f. Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on the site visit;

g. Failure to properly report analytical results in accordance with subrule 83.6(6).

83.7(4) *Procedure for revoking certification.*

a. The department will notify the party of its intent to revoke certification by commencement of a contested case proceeding as provided in 561—subrule 7.5(2) and consistent with Iowa Code section 17A.18.

b. Certification will be reinstated when the laboratory can demonstrate that all conditions for laboratory certification have been met through a new application for certification.

These rules are intended to implement Iowa Code sections 455B.113 to 455B.115.

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